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NOMINATION OF DONALD A. HENDERSON

HEARING

BEFORE THE

COMMITTEE ON COMMERCE SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED SECOND CONGRESS

FIRST SESSION

ON

DONALD A. HENDERSON, TO BE AN ASSOCIATE DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY POLICY

MARCH 5, 1991

Printed for the use of the Committee on Commerce, Science, and Transportation

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NOMINATION OF DONALD A. HENDERSON

TUESDAY, MARCH 5, 1991

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 9:07 a.m., in room SD-253, Hon. Al Gore, presiding.

Staff members assigned to this hearing: Pat Windham and Becky Kojm, professional staff members; and Leslie Blosse, minority professional staff member.

OPENING STATEMENT BY SENATOR GORE

Senator GORE. Good morning, and I would like to welcome Dr. Henderson and Senator Sarbanes. I have got a very brief statement that I wanted to make.

With Dr. Alan Bromley at OSTP, the Office of Science and Technology Policy, it has become a revitalized agency, providing strong leadership for the Executive Branch in such important areas of research as high performance computing, global change, mathematics and science education, and other fields.

Together, OSTP and Congress are creating effective, coordinated interagency research programs in these and other important areas.

One reason why OSTP has become more active and influential is that the President has followed Dr. Bromley's advice and nominated truly first-rate individuals to serve as OSTP's associate directors. This morning, the Commerce Committee is considering one such nomination, that of Dr. Donald A. Henderson, to be an associate director. If the Senate confirms Dr. Henderson, and we will, Dr. Bromley has said that this new associate director will focus primarily on life sciences issues.

Dr. Henderson brings eminent qualifications to this position. A physician by training, during the 1950's and 1960's he worked in the old Department of Health, Education and Welfare, where he specialized in communicable diseases and vaccination programs.

From November 1966 to January 1977, he served as director of the World Health Organization's global smallpox eradication program. As we all know, that program was a tremendous, outstanding success, one of the great achievements of this century. It eliminated from this planet one of the worst diseases known to human history and to humanity.

From February 1977 until just recently, Dr. Henderson served as Dean of the Johns Hopkins University School of Hygiene and Public Health. He now holds an endowed chair at the same school and is currently on leave from Johns Hopkins.

Among his many honors, Dr. Henderson has received the National Medal of Science, major awards from the World Health Organization and the Pan American Health Organization, awards and medals from Britain, Japan, and many other countries, and numerous honorary degrees.

Dr. Henderson, we are pleased and, indeed, privileged to welcome you to this confirmation hearing. I want to welcome your wife, Nana, who is in the front row there, and your daughter Leigh, and we are very pleased to have all of you here this morning.

I have an opening statement that Senator Hollings would like to have included in the record.

[The statement follows:]

OPENING STATEMENT BY THE CHAIRMAN

I am pleased that the Committee is holding this morning's hearing on the nomination of Dr. Donald A. Henderson to be an Associate Director of the Office of Science and Technology Policy (OSTP).

Dr. Henderson comes to this new post after a distinguished career in public health. In his work to eradicate smallpox and other communicable diseases, he has demonstrated that science can be used in ways which greatly benefit people's lives. I admire his dedication and skill, and I hope that if confirmed he will continue his efforts to use our government's investment in research in ways which meet the great problems of today. Our country faces serious difficulties in areas such as health, industrial competitiveness, and the environment, and our government needs officials who will confront these problems squarely and respond to them with imagination, determination, and compassion.

I look forward to hearing from Dr. Henderson today.

Senator GORE. It is a special privilege as well to welcome my distinguished colleague from Maryland, Senator Sarbanes, who will introduce our witness and we are pleased to hear from you at this time.

STATEMENT OF HON. PAUL S. SARBANES, U.S. SENATOR FROM MARYLAND

Senator SARBANES. Thank you very much, Mr. Chairman. I am very pleased to be here with you today and to have this opportunity to introduce Dr. D. A. Henderson, a friend of many years who has, as you have noted, been nominated for the post of Associate Director for Life Sciences in the Office of Science and Technology Policy at the White House.

Dr. Henderson is a very distinguished physician and scientist, and we in Maryland are very proud of his record both before he came to Maryland and since being Dean at the world-renowned Johns Hopkins University School of Hygiene and Public Health.

He brings to this position in the Office of Science and Technology Policy an extraordinary background in public health. Following his graduation in 1954 from the University of Rochester School of Medicine and the completion of a master's in public health degree at Johns Hopkins he worked for the Center for Disease Control in Atlanta, where smallpox eradication became the focus of his work.

In 1966, he joined the staff of the World Health Organization in Geneva, and for 11 years served as chief medical officer of the World Health Organization's international smallpox eradication program. That program, as we know, is an extraordinary success. It actually wiped out a disease. In 1977 when that program pretty well concluded the deanship at the Johns Hopkins School of Public Health fortuitously became open and D. A. Henderson came there to be the Dean.

His work, of course, has been recognized throughout the world. As you noted, in 1986 President Reagan gave him the National Medal of Science, our Nation's highest scientific honor. He has been honored by many countries throughout the

world, and by many universities. In fact, I have an article from the "Baltimore Sun," and the heading on it is, "Dr. Donald Henderson. He Led World Fight that Knocked out Smallpox."

His work around the world has been responsible for the saving of countless lives and the betterment of the health and environmental standards in many nations. I think it is fair to say that the thread that runs throughout his career is a total dedication to using medicine and science for the improvement of public health everywhere.

I have great confidence in his ability to contribute greatly to the formulation of national science policy. I frankly cannot think of anyone more qualified for the position of Associate Director for Life Sciences, and it is a privilege for me to join him here at the table today and to commend him and his extraordinary career to you.

Senator GORE. Thank you very much, Senator Sarbanes.

Listening to your statement made me think that really we could think of Dr. Henderson as the Norman Schwarzkopf of the battle against smallpox, because you knocked it out completely.

Senator SARBANES. That is a compliment to Schwarzkopf, too, the way you put it.

Senator GORE. Indeed it is, and to both of them, and we know that you have another hearing, Senator Sarbanes, and thank you very much for introducing our witness here.

Senator SARBANES. Thank you, Mr. Chairman.

Dr. HENDERSON. Thank you very much, Paul.

Senator GORE. Dr. Henderson, we are anxious to hear your statement and then we will have some questions, and then we will move toward a recommendation that you be confirmed. A mark-up is expected later this month. I cannot give you the exact date, but it will probably be soon.

We would have had this hearing before now except for the natural bureaucracy involved and the paperwork getting from the Executive Branch through the FBI and over to the Congress and so forth, but we have been waiting for this nomination and anxious to approve it, because we really do have such high regard for what you represent, what you have done.

I will include the biographical sketch and prehearing questions and your answers in the record.

[The biographical sketch and questions and answers follow:]

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United States Senate
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION
WASHINGTON, DC 20510-6125

STATEMENT FOR COMPLETION BY PRESIDENTIAL NOMINEES

(If more space is needed, please use attached REMARKS sheet)

A. BIOGRAPHICAL DATA

1. Name: Henderson (Last) Donald (First) Ainslie (Other)

   Address: 3802 Greenway (Current residence) Baltimore, MD 21218
   615 N. Wolfe Street (Business) Baltimore, MD 21205

2. Position to which nominated: Associate Director, Office of Science and Technology Policy
   Date of nomination: January 4, 1991

3. Date of birth: September (month) 7 (day) 1928 (year)
   Place of birth: Lakewood, Ohio

4. Marital status: Married
   Full name of Spouse: Nana Irene Bragg

5. Names and ages of children: Leigh Ainslie 36
   David Alexander 34
   Douglas Bruce 30

6. Education:

Institution	Dates attended	Degrees received	Dates of degrees
Oberlin College	9/46-6/50	A.B.	1950
University of Rochester School of Medicine	9/50-6/54	M.D.	1954
Johns Hopkins University Sch. of Hygiene and Public Health	9/59-6/60	M.P.H.	1960

7. Employment record: List all positions held since college, including the title or description of job, name of employer, location of work, and dates of inclusive employment.

From	To	Name of employer	Address	Type of work
7/54	6/55	Mary Imogene Bassett Hospital	Cooperstown, NY	Intern in Medicine
7/55	10/57	Communicable Disease Center, DHEW	Atlanta, GA	Chief, Epidemic Intelligence Serv
11/57	8/59	Mary Imogene Bassett Hospital	Cooperstown, NY	Resident in Medicin
7/60	6/61	Communicable Disease Center, DHEW	Atlanta, GA	Chief, Surveillance Section
12/65	10/66	Communicable Disease Center, DHEW	Atlanta, GA	Dir., Smallpox Proc West. & Cent. Afric
11/66	1/77	World Health Organization	Geneva, Switzerland	Dir., Global Small-pox Erad. Prog.
2/77	8/90	Johns Hopkins University	Baltimore, MD	Dean, School of Public Health
9/90	Present	"	"	Professor

8. Government experience: List any experience in or direct association with Federal, State, or local governments including any advisory, consultative, honorary or other part-time service or positions.

(See Attachment A)

9. Political affiliations activities: List all memberships and offices held in or financial contributions and services rendered to all political parties or election committees during the last 10 years

None

8. **Government Experience:**

Surgeon General's Advisory Committees on:
Influenza, Secretary, 1961-1963
Measles Vaccines, Secretary, 1963
Immunization Practice, Secretary, 1964-1966
Government Accounting Office:
Research and Education Advisory Panel to the Comptroller-General, 1977-1986
Advisory Board, Program Evaluation and Methodology Division, 1988-
Chairman, Mayor's Task Force on Environmental Carcinogens (Baltimore), 1977-1978
NASA - Planetary Protection Study Group, 1978
Department of Health and Human Services:
PHS Hospitals Ad Hoc Advisory Committee, 1978
Secretary's Committee on Influenza, Vice-Chairman, 1979
National Ethics Advisory Board, 1977-1980
CDC Programs and Policy Advisory Committee, 1978-1980
Immunization Practices Advisory Committee, Centers for Disease Control, 1982-1986
National Vaccine Advisory Committee, 1988-1989; Chairman, 1990-1991
Secretary's Council on Health Promotion and Disease Prevention, 1989-1990
Center for Infectious Diseases, Scientific Advisory Board, 1989-
Executive Office of the President, Office of Science and Technology:
Task Force for Science and Technology in Foreign Assistance, Chairman, 1980
Advisory Committee on Science, Technology and Development, 1978-1979
U.S. Agency for International Development, Research Advisory Committee, 1983-1990
U.S. Department of State:
Advisory Committee on Oceans, Environmental and Scientific Affairs, 1988-1991
U.S. Public Health Service, Commissioned Officer, 1955-1977

10. Memberships: List all memberships and offices held in professional, fraternal, scholarly, civic, charitable, and other organizations.

(See Attachment B)

11. Honors and awards: List all scholarships, fellowships, honorary degrees, honorary society memberships, and any other special recognitions for outstanding service or achievement.

(See Attachment C)

DONALD AINSLIE HENDERSON ATTACHMENT B

10. **Memberships:**

World Health Organization:
- Special Committee on Measles Vaccine, Consultant, 1963
- Scientific Group on Human Virus Vaccines, Member, 1965
- Global Commission for the Certification of Smallpox Eradication, 1978-1980
- Program Advisory Group for the Prevention of Blindness, 1978-1982
- Programme for Research and Training in Tropical Diseases, Scientific and Technological Advisory Committee, 1982-1984
- Caribbean Epidemiology Center, Scientific Advisory Committee, 1980-1983
- Expert Advisory Panel on Virus Diseases, 1976-
- Committee on Orthopoxvirus Infections, 1981-
- Consultant Group on Poliomyelitis Eradication, Chairman, 1988-

Pan American Health Organization:
- Technical Advisory Group on Immunization, Chairman, 1985-

American Journal of Epidemiology, Board of Overseers, Associate Editor, 1965-1977; Chairman, 1984-

Editorial Advisory Board, Bibliography of Bioethics, 1979 -

International Association for Maternal and Neonatal Health, Scientific Council, 1981-

Rotary Foundation of Rotary International, Polio Plus Advisory Committee, 1985-

Association of Academic Health Centers, Task Force on Health Promotion/Disease Prevention, 1989-

"AIDS Patient Care" magazine, Editorial Advisory Panel, 1987-

Institute of Medicine, National Academy of Sciences:
- AID Health Strategy Study, Steering Committee, 1978
- Steering Committee for the Study on Clinical Investigations in Developing Countries, 1978-1980
- Advisory Committee on Health, Biomedical Research and Development, Chairman, 1981-1983
- Steering Committee, Study of Tropical Diseases, 1984-1987
- Committee on the Evaluation of Poliomyelitis Vaccine, 1987-1988
- Board on International Health, 1988-

Charles A. Dana Foundation Awards Jury, 1990-

10. **Memberships** (continued):

Foundation for Development of International Health (Japan), Scientific Consultant, 1990-
Instituto Nacional de Salud Publica (Mexico), Academic Advisory Committee, 1988-
Indian Institute of Health Management Research Board, 1985-1990
Maryland Society for Medical Research Board, 1978-
Population Crisis Committee Board, 1981-1991
International Center for Diarrheal Disease Research (Dhaka) Board, 1988-1991
Medical Alumni Association Board, Mary Imogene Bassett Hospital, 1989-
American Public Health Association:
  Committee on Hepatitis, Chairman, 1961-1965
  Multiple Antigen Committee, 1964-1966
  Epidemiology Section Council, 1965-1967
National Research Council, National Academy of Sciences:
  Board on Science and Technology in International Development, 1981-1983
  Committee on Research Grants, 1982-1983
Harvard University:
  Visiting Committee, University Health Services, 1981-1985
Burroughs-Wellcome Fund, Pharmacoepidemiology Awards Committee, 1983-1987
City University of New York Medical School, National Visiting Committee, 1986-1990
American Board of Preventive Medicine, 1963-
American College of Epidemiology, Fellow, 1990-
American College of Preventive Medicine, Fellow, 1978-
American Epidemiological Society, 1963-
American Public Health Association, 1956; Fellow, 1961-
American Society of Tropical Medicine and Hygiene, 1981-
Association of Schools of Public Health, Treasurer, 1978; Vice President, 1981-1982; 1987-1988; President, 1988-
Indian Society for Malaria and Other Communicable Diseases, Fellow, 1975-
International Epidemiological Association, 1965-
Royal College of Physicians (Edinburgh), Fellow, 1986-
Royal Society of Tropical Medicine and Hygiene, Fellow, 1976-

11. **Honors and Awards:**

Honorary Sc.D., University of Rochester, 1977
Honorary LL.D., Marietta College, 1978
Honorary Sc.D., University of Illinois, 1979
Honorary Sc.D., University of Maryland, 1980
Honorary M.D., Universite de Geneve, 1980
Honorary L.H.D., State Universtiy of New York, 1981
Honorary Sc.D., Yale University, 1986
Honorary Sc.D., Albany Medical College, 1989

American Scientific Awards and Recognition:

National Medal of Science, 1986
National Academy of Sciences Public Welfare Medal, 1978
Charles S. Dana Foundation Award for Pioneering Achievement in Health, 1986
Elected to the American Academy of Arts and Sciences, 1986
Elected to the Institute of Medicine, National Academy of Sciences, 1978
Albert Schweitzer International Prize for Medicine, 1985
American College of Physicians James D. Bruce Memorial Award, 1978
American Public Health Association Rosenhaus International Award for Excellence, 1975
American Academy of Pediatrics Honorary Fellow, 1980
Johns Hopkins University Distinguished Alumnus Award, 1982
Michigan State University Walter F. Patenge Medal of Public Service, 1984
Vanderbilt University School of Medicine Medal, 1990
Ohio Foundation of Independent College, Hall of Fame, 1990
Blue Cross-Blue Shield 50th Anniversary Distinguished Service Award, 1979
U.S. Association for the United Nations Joseph C. Wilson Award in International Affairs, 1978
U.S. General Accounting Office Comptroller General's Special Recognition, 1986
U.S. Department of Health and Human Services:
Superior Service Award, 1964
Sustained Superior Performance Award, 1966
U.S. Public Health Service:
Commendation Medal, 1962
Distinguished Service Medal, 1976
Elected to Delta Omega Honorary Public Health Society, 1979; Outstanding Alumnus Award, 1980
Electecd to Sigma Xi, 1956

11. **Honors and Awards** (continued):

Foreign Scientific Awards and Recognition:

World Health Organization Health for All Medal, 1990
Pan American Health Organization Honor Award, 1990
British Medical Association Foreign Corresponding Member, 1990
The Japan Prize, 1988
Republic of China Health Medal of the First Grade, 1988
Government of Uruguay Medal of Abnegation, 1988
Universidad Peruana Cayetano Heredia, Honorary Professor, 1988
Commemorative Award of Seventh World Congress of the International Physicians for the Prevention of Nuclear War, 1987
Gairdner Foundation (Canada) International Award of Merit, 1983
Royal Colleges of Physicians of the United Kingdom, Faculty of Community Medicine, Honorary Fellow, 1981
Royal Society of Medicine:
Richard T. Hewitt Award, 1986
Honorary Member, 1980
London School of Hygiene and Tropical Medicine and Royal Society of Tropical Medicine and Hygiene George McDonald Prize and Medal, 1976
Government of Ethiopia Medal for Contributions to Health, 1979
Goverment of Afghanistan *Roghtya Neshan* (Health Medal), 1976
Ernst-Jung Foundation (Germany) *Ernst-Jung Preis fur Medizin*, 1976
Government of India Special Award, 1975
Indian Society for Malaria and Other Communicable Diseases Special Award, 1975
Lahore, Pakistan, Certificate of Merit, 1977

PREHEARING QUESTIONS OF THE CHAIRMAN AND THE ANSWERS THERETO

1. If confirmed as Associate Director of the Office of Science and Technology Policy (OSTP), what will be your principal responsibilities and activities?

ANSWER: My responsibilities would pertain to the Life Sciences area, including basic and clinical research in biomedical and behavioral disciplines, agricultural research, research on environmental matters as they pertain to agriculture and human health, and the field of biotechnology. My most important responsibility would be to provide the President, through Dr. Bromley, with the best available advice on science and technology for policy, and on policy for science and technology. The President has requested that "OSTP play a central role in developing and coordinating Federal science and technology strategies, and in analyzing cross-cutting issues in research and development." As an Associate Director of OSTP, I would expect to cooperate with staff of the Office of Management and Budget (OMB) in developing the President's budget request for future years and would interact throughout the budget cycle.

It is Dr. Bromley's practice to involve the four associate directors in the range of issues addressed in OSTP in a collegial and flexible manner. Thus, while each has primary areas of responsibility, all four associate directors have opportunities to contribute across the spectrum of OSTP activities.

2. What do you see as the Nation's principal life sciences and public health issues, and what role do you see OSTP playing in the creation and implementation of Federal policies regarding these issues? If confirmed, what would be your two or three highest priorities?

ANSWER: OSTP has played an important role in developing and coordinating biotechnology policy but much remains to be done in a field which offers so much potential but which is scarcely out of its infancy. If confirmed, I fully anticipate that a substantial proportion of my own time and that of the Division of Life Sciences would be devoted to coordinating activities in and facilitating the development of this field which is so important to health, agriculture and the environment as well as our own economic vitality.

A second area of importance is the human genome project which promises to have far-reaching impacts on many problems in human health. Coordination of activities both within government and with other governments promises to be a continuing challenge for OSTP.

A third and related area of importance is the health and vitality of biomedical research — to assure an appropriately supported community of scientists working within an infrastructure which is physically suitable in size and satisfactorily equipped, and with provision for training and development programs to assure the continuing invigoration of the research community. Drawing upon studies which assess opportunities, resources and needs, I would hope that better estimates of resource needs might be developed as well as a broad consensus as to the balance of resources to be assigned to investigator-initiated research, special categorical research programs, infrastructure support and training. A reasoned government-wide framework to address the uncommon but lamentable episodes of scientific misconduct would be part of the agenda.

Vaccine development, production and application commands special attention. Cost-benefit analyses, whether measured in terms of mortality or treatment costs, document clearly that immunization in this and other countries is the single most effective instrument in our medical armamentarium. At the same time, it is the simplest of medical procedures. The substantial groundwork which basic research has laid indicates clearly that there are many additional protective vaccines which could be produced and which could be effective with only one or two doses, perhaps relying more heavily on oral administration. For AIDS, a vaccine is probably the only fully satisfactory solution for this vexing problem. There are numerous impediments, however, which deter full exploitation of the inherent potential of immunization — costs and difficulties of field testing, regulatory constraints, basic research needs for development of vaccines for predominantly third- world infectious disease problems, difficulties which industry has in recouping research and development costs and the need for improved, practical strategies for vaccine administration. Strategic plans and programs are needed which incorporate talents and resources from several departments and agencies of government, as well as private and other public sector groups. OSTP should play a seminal role in assuring the development of appropriate strategies and initiatives.

One other categorical imperative which needs to be noted is the challenge, only recently becoming apparent, of new and emerging microbial agents, as exemplified by AIDS, cholera in Peru (the first epidemic of cholera in the West Hemisphere in this century), dengue hemorrhagic fever in the Caribbean and Latin America and Lyme disease. With our better understanding of microbial genetics and replication, it is now apparent that we will be required to cope indefinitely with an ever-changing array of new or emerging microbial agents, some of which could pose major threats to human survival. This is an international problem demanding international responses. Because of the extensive biomedical and epidemiological resources in this country, the U.S. is called upon to assume a leadership role. How best to do this remains to be worked out.

3. Are you currently considering or pursuing any other job opportunities that might lead you to leave OSTP at any time within the next two years?

ANSWER: I am not considering nor, to my knowledge, am I being considered for any other job than that of Associate Director of OSTP. I would fully expect to continue in this position for at least two years subject, of course, to the wishes of the President.

4. What size staff do you anticipate having, and how will they be organized ? For example, how many Assistant Directors and professional staff would report to you, and what would be their principal activities?

ANSWER: For the Division of Life Sciences, we would have one Assistant Director in biotechnology, two policy and program analysts plus two office support staff. Each of the professional staff would report directly to me. One of the program analysts would be primarily responsible for science and technology issues as they pertain to agriculture; the other would have responsibility for areas of biomedical research other than those specific to biotechnology. I expect also to participate with Dr. Bromley and the other associate directors in all major matters coming before OSTP.

5. Over the past decade, OSTP has overseen a Biotechnology Science Coordinating Committee (BSCC) that has reviewed Federal policies regarding biotechnology research and the regulation of new products produced through biotechnology. Recently, however, the Vice President's Council on Competitiveness has been involved in this issue. What is the relationship, if any, between the BSCC and the Vice President's work on biotechnology issues? Which group within the Executive Office will now have the lead in developing biotechnology policy, OSTP or the Vice President's Council?

ANSWER: In answering this question, it is useful to review the history of the origins of the Biotechnology Science Coordinating Committee (BSCC) and its successor, the Biotechnology Research Subcommittee (BRS), under the Federal Coordinating Council on Science, Engineering, and Technology (FCCSET) Committee on Life Sciences and Health.

Interagency coordination of biotechnology regulation began in the Cabinet Council on Natural Resources and the Environment, Working Group on Biotechnology. When the Cabinet was reorganized in January 1985, the Working Group was placed under the aegis of the Domestic Policy Council. The Working Group identified a need for uniformity and consistency of Federal regulations for the emerging biotechnology industry. Therefore, in November 1985, the BSCC was established to provide a forum for interagency scientific coordination on these matters. The BSCC was chartered under FCCSET and reported to the Director of the Office of Science and Technology Policy.

As described in its original charter, the BSCC was established in order to:

Serve as a coordinating forum for addressing scientific problems, sharing information, and developing consensus;

Promote consistency in the development of Federal agencies' review procedures and assessments;

Facilitate continuing cooperation among Federal agencies on emerging scientific issues; and

Identify gaps in scientific knowledge.

A basic assumption was, that a common knowledge base and a discussion forum in which new scientific questions could be raised, would result in agreement on management of these issues through regulations that would be consistent across agency boundaries.

However, as is apparent from the charter, regulation was not the principal focus of the BSCC and later charters reflected the intention to use this body as a vehicle for sharing information and developing a coordinated biotechnology program across agency boundaries. The Committee proved useful for the development of guidelines for regulation but, unfortunately, had little time to devote to other activities.

Last year, as part of the reorganization and revitalization of FCCSET, the BSCC was renamed the Biotechnology Research Subcommittee and placed under the FCCSET Committee on Life Sciences and Health. The emphasis of the BRS will be on issues of science and research related to biotechnology. The membership of the Subcommittee has been expanded as a reflection of this broadened emphasis.

I would expect that the BRS, as part of its advisory role to the OSTP Director and the Executive Office of the President, will be called upon to review proposed regulations and guidelines as they are developed. However, the BRS review will focus on the scientific aspects of these proposals. One of the first goals of the BRS will be to develop an accurate picture of current Federal support for biotechnology research and research training. This is recognized as a necessary step in analyzing our strengths and weaknesses and deciding how to address the research needs of this field.

OSTP has worked closely with the Council on Competitiveness and, in fact, Dr. Wyngaarden, the previous OSTP Associate Director for Life Sciences, served as the first chairman of the Biotechnology Working Group. Since his departure, the OSTP Assistant Director for Life Sciences has served as Vice Chairman of the Working Group.

In general, I envision the BRS, through OSTP, providing the necessary scientific input to the Executive Branch on biotechnology policy development. In addition, OSTP will continue to cooperate with the Council on Competitiveness in its deliberations of broad policy issues related to biotechnology competitiveness. This seems to be working well and I see no reason to change the status quo.

6. If confirmed, what role do you anticipate that you will play in coordinating the various agencies involved in the Human Genome Project?

ANSWER: The principal agencies involved in the Human Genome Project are the National Institutes of Health and the Department of Energy. In addition, the National Science Foundation and the Department of Agriculture support research programs aimed at elucidating the genomes of complex organisms in the field of agriculture. Because this is an interagency effort, OSTP is involved in ensuring that appropriate coordination mechanisms are in place and are working effectively.

In October 1988, NIH and DOE signed a Memorandum of Understanding that outlined areas of mutual interest and identified opportunities for joint activities. It is my understanding that this agreement is working well. For example, each agency has appointed members to joint advisory committees that set goals and directions for research programs, while carefully defining agency roles in attaining those objectives. Moreover, the constant communication between agencies has provided the means to maximize the use of input from experts in the field, while minimizing duplication of effort. There has been a synergistic impact on the programs and resources of all the interested agencies as a result of the interagency discussions of technological advances; of potential social, legal and ethical impacts of this research; and of the need for making the optimal use of federal resources. Such resources include supercomputers, genetic data and specimens from extended families, as well as funds and facilities.

OSTP's role will be to continue to monitor the progress in meeting the goals outlined in the joint NIH/DOE five-year plan and to assist in coordinating international and interagency activities.

Dr. Bromley has on several occasions, before this Committee and other Committees of the Congress, noted the need for developing a broad, international approach to the megaprojects in the basic sciences. The human genome project falls within this category, and I hope it will receive the attention it deserves.

7. As an expert on epidemics and vaccines, how would you characterize the progress to date in dealing with AIDS? Have the United States and other countries made much headway in preventing new cases and in finding treatments for those people who develop the disease? And do you have any estimate of when an effective vaccine may be developed?

ANSWER: Significant progress has been made in gaining a basic scientific understanding of the human immunodeficiency virus and of the disease, AIDS. Many research projects are in progress which offer promise for new specific treatments for HIV infection as well as the complications that arise from HIV infection. The social sciences have advanced significantly our knowledge of important behavioral factors as well as the economic and social consequences of the disease. Of special importance is the fact that substantial progress is now being made in vaccine development.

Unfortunately, the disease continues to spread globally. In the United States the rate of new infections has decreased among recipients of blood and blood projects as well as among homosexual men but not in other groups at risk. The rate of new infections is increasing among intravenous drug users, their heterosexual partners, and children born of either intravenous drug using women or women whose heterosexual partners are IV drug users. We are now observing a shift of the epidemic to inner city areas and an increasing proportion of cases among minorities and the disadvantaged. Globally, the epidemic is spreading steadily with little evidence of satisfactory control in the developing countries. Infection rates among the general population in some African countries exceeds 10%. There is no question but that the epidemic will have serious effects on the economies as well as the sociopolitical structures of many of these countries.

Efforts directed toward prevention and treatment have so far met with only limited success. World-wide, preventive measures rely primarily on educational campaigns which have been aimed at modifying high risk behaviors and on procedures to protect the blood supply. Educational efforts have not been notably successful, with some few exceptions among selected subpopulations at risk. There is one approved and licensed drug for treatment of HIV infection (zidovudine or AZT) and a number of other promising drugs that are being tested in clinical trials. However, we do not appear to be close to finding a "cure" for AIDS. These drugs, notably AZT, have been successful only in slowing the progression of AIDS in people who already have the disease as well as delaying the onset of disease in those who are infected but who have not yet developed symptoms. However, this effect has only lasted for 18 months to 2 years on average. Given the difficulties in effecting behavioral change, it is becoming increasingly clear that prevention of infection is the most important and perhaps the only possible modality which will be successful in controlling spread, especially in developing countries. A safe and effective vaccine is, in brief, the key to containment of the epidemic.

Over the past 2 years there has been substantial progress in vaccine research using animal models, specifically the development of a vaccine for simian immunodeficiency virus infection, the monkey equivalent of the human AIDS infection. Three separate studies have demonstrated protection against challenge with the live virus after immunizing monkeys with killed virus preparations. From the results of comparable studies in humans, it now appears feasible to develop a safe and protective human vaccine. Currently there is an intensive effort both at the basic science level and at the level of targeted vaccine development to develop a satisfactory vaccine. There are now a number of vaccines in phase I trials in humans which have demonstrated their safety and their ability to induce a serological response against the virus. However, their efficacy has not yet been proven. Over the next several years, the National Institute of Allergy and Infectious Diseases hopes to have in place trials of a number of vaccine candidates which will prove safe and effective. Although one cannot predict with certainty when a commercial product will emerge, scientists are now hopeful that a vaccine can be developed within this decade.

8. Over the past year, we all have heard reports of American children developing measles and other diseases because they have not been vaccinated. Many of these children come from poor families. In your opinion, how has the United States come to such a point that many children do not receive basic vaccinations? What effort, if any, is this Administration making to remedy this problem? Has the Administration set the goal of ensuring that all American children receive basic vaccinations, and, if so, what resources are being committed to this effort?

ANSWER: Most children do receive their childhood vaccinations, but many receive them too late to be of maximum benefit. Because all States require children attending school, headstart programs and licensed child care facilities to be vaccinated as a condition of matriculation, these children are well protected. However, we are not doing well in reaching preschool children, particularly in the inner cities, to ensure they have received their immunizations on time. In some cities, immunization levels are unacceptably low, as low as 50-60% among two-year-olds, and this is the reason for the measles epidemics now occurring.

From as yet incomplete studies reported to the National Vaccine Advisory Committee, a Committee which I have chaired, important problems appear to rest with health care providers and health systems which create barriers to immunization. The evidence is largely anecdotal as yet; quantitative studies are now in progress through the Centers for Disease Control. The Committee has been informed, for example, that many public sector clinics require a physical examination before vaccination (contrary to national advisory committee recommendations) and require that visits for vaccination be scheduled well in advance. The concept of checking vaccination records and immunizing unvaccinated children whenever seen by a health care provider is not a policy followed by many general and acute care clinics. Moreover and contrary to national recommendations, mild illnesses are considered as contraindications to vaccination and, because of these, children are denied vaccination. For children in the private sector, it has been reported that many third party payers and health maintenance organizations do not cover the costs of vaccine or vaccination. Accordingly, many private practitioners refer patients to already overtaxed clinics. And, finally, many clinics are not open during hours convenient to working parents. In brief, the infrastructure for vaccine delivery must be characterized as anything but "user friendly."

It is important to note, parenthetically, that there is clear evidence to indicate that the current measles vaccine is fully efficacious and that there is no evidence for genetic changes of significance in the naturally occurring measles virus itself. Moreover, vaccine program managers have reported

that adequate funds are available to supply needed vaccine. In brief, adequate quantities of an effective vaccine are available. They are not reaching potential recipients.

The fundamental cause for what appears to be a deteriorating immunization program can only be speculated upon, but almost certainly it reflects, in part, a sense of complacency about immunization given the very low levels of vaccine-preventable diseases during recent years.

The National Vaccine Advisory Committee made a number of recommendations and these are now being vigorously implemented. In cooperation with pediatric and primary care professional organizations and the Children's Defense Fund, the PHS has widely publicized the seriousness of the problem and the Committee's recommendation that all children, whenever seen by a health provider, should have their immunization records checked and appropriate vaccinations given irrespective of the presence of minor illnesses. PHS has begun pilot programs to integrate the delivery of vaccines with the provision of other Federal and state funded services. Studies have begun in three cities to ascertain more explicitly the specific barriers to immunization so as to develop more precise strategies. Meanwhile, laboratory and field studies are monitoring the genetic structure of the measles virus and the efficacy of available vaccines in order to assure that it continues to provide good protection.

The Administration is committed to significantly reducing childhood diseases preventable by the use of vaccines. In its "Year 2000 Objectives for the Nation," the Public Health Service anticipates the reduction of indigenous cases of diphtheria, tetanus, measles, rubella and polio to zero. There are projected to be no more than 500 cases of mumps and fewer than 1000 cases of pertussis among children five years of age and younger.

In FY 1990 the Centers for Disease Control began its Infant Immunization Initiative, which has as its goal complete immunization of 90 percent of U.S. children by age two years. For FY 1991, the Administration will spend through the Public Health Service, $368.6 million for vaccine research, development and other immunization related activities. This represents a 17 percent increase over the previous year. A similar increase is proposed in the President's 1992 budget now before the Congress.

9. How large an effort is the Federal Government now making to find new medical and psychological methods for dealing with drug addiction? At that rate of effort, when might this country expect to develop effective therapies to cure addiction and to block the urge for drugs such as cocaine?

ANSWER: The Federal Government is currently spending over $225 million on basic, clinical and applied research to discover new biomedical and behavioral approaches for the treatment of drug addiction, primarily through the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) and, in particular, its National Institute on Drug Abuse (NIDA). Significant progress is being made but the difficulty of developing new and novel treatments for drug addiction that can effectively reach a wider variety of patients at reduced cost should not be underestimated.

From fundamental research based on the neurobiological bases of addiction, it would now appear possible to develop a range of new medications to treat addictive disorders. Accordingly, NIDA established a Medications Development Program in 1989 to capitalize on this new knowledge base. The funding for this specific program in FY 1991 is approximately $40 million. The development of new medications for any purpose, however, is a time consuming and expensive proposition, typically taking 10 years or more and costing as much as $230 million from discovery to marketing. NIDA hopes some products can be developed sooner and at less cost than this by giving priority to compounds on which considerable work has already been done, by cost sharing with industry, and by promised fast track review of medications by the Food and Drug Administration.

Medications to treat addiction to various drugs may not, in and of themselves, "cure addiction" or "block the urge for drugs" but may contribute substantially to those goals by stabilizing patients and allowing them to normalize their lives. Such treatments could dramatically reduce the spread of HIV through the population by reducing needle-sharing and sex for drugs behaviors which are prevalent in addict populations.

Medications are being sought and/or developed in several areas: (1) to reduce or eliminate "craving" for specific drugs and the potential for relapse; (2) to block the effects of abused drugs; (3) to reduce or ameliorate withdrawal syndromes; (4) to block or reverse the toxic effects of abused drugs; and (5) to substitute less toxic medications which have less potential for abuse. Currently, clinical trials of drugs for both opiate and cocaine treatment are in progress with products which have already undergone safety testing because of their use for other medical indications. If these trials show significant efficacy, the drugs could be marketed within 3-4 years. A second series of compounds without an established record of human safety may take 3 to 10 years before being available for marketing.

A Commission on Medicines for the Treatment of Drug Dependence and Abuse has been established which serves to bring together government, academic, and private sector scientists. Over the coming years, NIDA expects industry to offer far more compounds than have been available in the past. Similarly, a solicitation of academic programs in chemistry and pharmacology has already resulted in more compounds being submitted for testing.

10. Great anxiety has developed within the biomedical research community over a perceived crisis of research funding, Money appropriated for the National Institutes of Health (NIH) has risen sharply over the past decade, but so has the number of biomedical researchers. In your view, what is the major problem here.: does the country devote too little funding to biomedical research, or has the country

produced too many biomedical researchers? What do you believe is the appropriate number of biomedical researchers for the United States?

ANSWER: At the outset, it is to be noted that the Federal government now supports more principal investigators at universities than ever before, reflecting real increases in constant dollars in the level of Federal support for academic research. However, the number of researchers competing for funds has increased more rapidly — in part, a result of the emergence of new and steadily expanding scientific opportunities as well as past successes in training high quality doctoral-level scientists. Data show that the budget for biomedical research funding has not grown so rapidly as the number and cost of meritorious projects competing for funds.

The problem is compounded by the fact that individual investigator-initiated grants have both increased in size and in duration during recent years. Increases in the size of grants reflect inflation plus an added amount resulting from the increased complexity and expense of instrumentation and reagents — so-called "sophistication inflation." During recent years, grants of longer duration have been made, at the request of the research community, in order to increase the stability of support, thereby reducing the fraction of time and effort a researcher devotes to paperwork. While both of these changes have merit, they create out-year commitments which reduce the pool of money available for new and competing proposals and result in increased competition for uncommitted research funds.

Other factors need to be considered in order to assess the problem accurately. Although it is fact that the number of biomedical research grant applications has increased, rising about 30 percent over the past 10 years, responses within the research community unintentionally serve to distort comparisons with earlier years. It has been found that the number of grant applications resulting from amended applications has risen significantly—from an historical rate of about 8% to a rate of 30 to 35% today. Also the number of multiple applications submitted by investigators has increased. Currently about 10 to 12 percent of researchers submit more than one application in a fiscal year, compared to an historical rate of about 3 percent.

An interagency group under the Federal Coordinating Council for Science, Engineering, and Technology (FCCSET) has been established to consider these and other issues. It is called the Working Group on the Structure of the Support of Science and is chaired by James Hayes of the National Science Foundation. Its initial task, it will seek to obtain more comprehensive statistical data and to evolve more effective indices for policy purposes. With firmer data bases in hand, the important questions can be addressed as to how much money should be allocated and how many biomedical researchers should be supported.

ADDITIONAL PREHEARING QUESTIONS FROM SENATOR HOLLINGS (ON BEHALF OF SENATOR KENNEDY)

1. As one of only a handful of physicians working in the White House, how do you foresee your role in the overall health policy development process?

ANSWER: My principal responsibility must inevitably be that of discharging OSTP obligations in fulfilling the President's request that "OSTP play a central role in developing and coordinating Federal science and technology strategies in analyzing cross-cutting issues in research and development." Because of my experiential background, I tend to view science and technology within its broader context of developing practical solutions for problems of illness and premature mortality. My special interest is in disease prevention and health promotion. The President's budget this year highlights the importance of disease prevention and, indeed, this strikes a resonant chord throughout this and other countries. I would hope that the rewarding and instructive experiences which I have had in the World Health Organization and at Johns Hopkins in promoting programs which more closely relate science and application might contribute to a broader array of policy initiatives which foster more effective disease prevention and health promotion activities.

2. OSTP has been involved with issues such as biotechnology, seafood safety and scientific misconduct. Are these areas where you would foresee continued involvement, and what are some other life sciences areas where you believe OSTP should play a role?

ANSWER: OSTP has played an important role in developing and coordinating biotechnology policy but much remains to be done in a field which offers so much potential but which is scarcely out of its infancy. If confirmed, I fully anticipate that a substantial proportion of my own time and that of the Division of Life Sciences would be devoted to coordinating activities in and facilitating the development of this field which is so important to health, agriculture and the environment as well as our own economic vitality.

A second area of importance is the human genome project which promises to have "far-reaching impacts on many problems in human health. Coordination of activities both within government and with other governments promises to be a continuing challenge for OSTP.

A third and related area of importance is the health and vitality of biomedical research - to assure an appropriately supported community of scientists working within an infrastructure which is physically suitable in size and satisfactorily equipped, and with provision for training and development programs to assure the continuing invigoration of the research community. Drawing upon studies which assess opportunities, resources and needs, I would hope that better estimates of resource needs

might be developed as well as a broad consensus as to the balance of resources to be assigned to investigator-initiated research, special categorical research programs, infrastructure support and training. A reasoned government-wide framework to address the uncommon but lamentable episodes of scientific misconduct would be part of the agenda.

Vaccine development, production and application commands special attention. Cost benefit analyses, whether measured in terms of mortality or treatment costs, document clearly that immunization in this and other countries is the single most effective instrument in our medical armamentarium. At the same time, it is the simplest of medical procedures. The substantial groundwork which basic research has laid indicates clearly that there are many additional protective vaccines which could be produced and which could be effective with only one or two doses, perhaps relying more heavily on oral administration. For AIDS, a vaccine is probably the only fully satisfactory solution for this vexing problem. There are numerous impediments, however, which deter full exploitation of the inherent potential of immunization—costs and difficulties of field testing, regulatory constraints, basic research needs for development of vaccines for predominantly third-world infectious disease problems, difficulties which industry has in recouping research and development costs and the need for improved, practical strategies for vaccine administration. Strategic plans and programs are needed which incorporate talents and resources from several departments and agencies of government, as well as private and other public sector groups. OSTP should play a seminal role in assuring the development of appropriate strategies and initiatives.

One other categorical imperative which needs to be noted is the challenge, only recently becoming apparent, of new and emerging microbial agents, as exemplified by AIDS, cholera in Peru (the first epidemic of cholera in the West Hemisphere in this century), dengue hemorrhagic fever in the Caribbean and Latin America and Lyme disease. With our better understanding of microbial genetics and replication, it is now apparent that we will be required to cope indefinitely with an ever-changing array of new or emerging microbial agents, some of which could pose major threats to human survival. This is an international problem demanding international responses. Because of the extensive biomedical and epidemiological resources in this country, the U.S. is called upon to assume a leadership role. How best to do this remains to be worked out.

3. Are there areas of the Prevention Initiative in the President's 1992 Budget that you think could be further expanded, or additional areas that could be included within this proposal?

ANSWER: The President's Prevention Initiative represents an important new departure in highlighting and proposing substantial budget increases for a range of important activities directed at disease prevention and health promotion. For most of these, the Federal funds are basically intended to catalyze or facilitate a broad array of state, local, private sector and personal initiatives. They are directed toward achieving goals set forth in the Department of Health and Human Services 1990 book, Healthy People 2000: National Health Promotion and Disease Prevention Objectives. Experience gained in endeavoring to reach these goals will require a regular review of strategy and expenditures in each of the categories. In time, a variety of other prevention initiatives can be foreseen, based on developments in research and experience with pilot prevention programs in this and other countries. As I see it, this new Initiative represents an important point of departure rather than an as yet all-inclusive program.

4. To improve public health and safety over both the short and long term, how should priorities be balanced between basic biomedical research, such as virology and molecular biology, and health promotion and disease prevention activities, such as prenatal care, immunizations, and smoking cessation.

ANSWER: I believe that basic biomedical research and health promotion/disease prevention activities should not be viewed as entirely separate and competing sets of activities but, rather, complementary ones. With a better fundamental understanding of disease causation and pathogenesis, it will be possible to develop and apply a much wider array of interventions with greater facility. For example, recent reviews by the Institute of Medicine and the National Vaccine Program suggest that we should be able to develop as many as 10 to 15 new vaccines by the end of this decade. Recent research suggests that many of these, as well as older vaccines, should be able to be given by mouth, rather than by injection, and much sooner after birth in order to protect the more vulnerable, young infant. Likewise, it would appear that vitamins such as beta carotene and Vitamin E, and perhaps other substances as well, may play such an important role in cancer prevention as to recommend them for general dietary supplementation. The availability of such interventions could materially reorder the strategy and tactics in prevention programs.

Certainly, it is important that preventive measures be fully utilized and implemented when they become available. This year, the President's budget specifically highlights a broad-based set of prevention initiatives and proposes substantial budget increases for each.

5. What should be the Federal role in promoting biotechnology as a safe and effective tool for improving national and world health, and at the same time invigorating the United States economy?

ANSWER: The potential of biotechnology represents a great new frontier which we have only begun to explore. Its foundation is based in new tools and concepts which make the exploration of the cell fully as exciting and full of potential as the exploration of space. The tools and concepts have begun to be applied widely—in the health care industry, in plant and animal agriculture, and in prevention and control of environmental pollution. For example, a growing proportion of new drugs

approved for treating life-threatening diseases are biotechnology products. In many cases, such diseases may be prevented altogether through the development and application of vaccines constructed with engineered antigens. Enzymes made in cell culture systems promise to change the way specialty chemicals are synthesized, making them cheaper and cleaner. Plants genetically altered to resist insect damage can free farmers from the need to use environmentally hazardous chemical pesticides. Already, bacteria are being employed to clean the environment and to mine ore. These examples demonstrate the extraordinary potential that biotechnology offers to improve not only human and environmental health, but the overall quality of life for the world's population. There are a number of ways in which the Federal government can play a role in ensuring public access to the benefits of this technology.

New biotechnology products emerge from a pipeline that begins with basic research and includes many phases of technological development before commercial scale production is possible. In the health field, basic biomedical research, largely supported by the Federal government through the National Institutes of Health, is responsible for the creation of the "new biotechnology" upon which industrial developments rests in genetics, molecular biology and immunology. The United States leads the world in most areas of commercial biotechnology primarily because U.S. scientists have made the largest number of relevant basic discoveries. It follows that the first requirement for our continued leadership is a steady flow of investigators in both academic and industrial settings, as well as education for the next generation of biotechnologists.

Although the U.S. has traditionally led the world in the generation of new scientific knowledge, other countries (especially Japan) have been more effective in coupling research with development and commercialization. The most difficult phase in the route from laboratory to market (in the U.S.) is the first step outside of the laboratory. In biotechnology the progressive steps of scale-up from test tube to flask to small fermentation vessel to large scale production facilities involve new scientific questions at each step because one is dealing with living cells that are vulnerable to shear forces, temperature, and oxygen regulation, growth conditions, inhibiting effects of metabolic by-products and other factors.

These are generic issues of biotechnology research, which are prohibitively expensive for each small entrepreneurial firm to address independently. For this reason, the recent Report on National Biotechnology Policy (February 1990) of the President's Council on Competitiveness identified scale-up research as an area for particular attention. As part of this effort, efficient technology transfer from the Federally-supported laboratories to the private sector will be important to maximize the return on the public investment in fundamental research.

Because biotechnology is being used to develop food and health care products, as well as mechanisms for environmental bioremediation, its regulation is handled by three agencies—EPA, USDA, and FDA. A strong, science-based regulatory system that is consistent across agency boundaries is essential for the credibility of the federal oversight process. Public assurance that the safety of health and the environment is crucial to the government and, I might add, to the industry. If consumers are not sure products are safe they will not buy them. Therefore, it behooves us to provide adequate resources to the regulatory agencies and to watch their performance very carefully.

Among the technologies, biotechnology is unusual in that its existing and potential applications extend across a broad variety of industrial sectors. However, it is not unique among newly emerging technologies in its need for a receptive financial environment in order to flourish. Although these aspects are beyond the immediate purview of the role of OSTP, recommendations in the Competitiveness Council Report point the way for use of biotechnology to invigorate the U.S. economy.

Issues that are important to maintaining our current leadership role include the provision of intellectual property protection, access to capital and a favorable climate for long-term investment, and application of a risk-based, scientifically sound regulatory system that ensures the health of the people and the environment without adding unnecessary oversight burdens. I share the Administration's and Congress' commitment to identifying and eliminating the barriers to future leadership in biotechnology.

6. The cost of health care is among the leading health problems in the United States. What role do you think that OSTP can play in addressing this issue, and what role do you see technology assessment and effectiveness research playing in controlling health care expenditures?

ANSWER: The escalating costs of health care unquestionably represent one of the most critical problems confronting the United States today. Given the fact that available diagnostic tools and possible therapeutic modalities are increasing exponentially, there is no cause to believe that medical care costs will stabilize, let alone abate, for the foreseeable future. In saying this, it should be recognized that advances in medical research can and do eventuate in cost savings but our increasing ability to alleviate symptoms of or to cure many more hitherto untreatable conditions inevitably results in higher expenditures.

More effective preventive modalities are now becoming available as biomedical research serves to define more clearly the pathogenesis of many diseases and identifies new approaches for intervention. In terms of costs and benefits, such research is highly advantageous in contributing to the aggregate of years of productive life and should be given high priority. It would be my hope that OSTP could play a role in catalyzing such support, especially in the areas of vaccine development, nutrition and behavioral change.

In my opinion, technology assessment and effectiveness research needs to be addressed far more seriously than they have been to date. I believe they can help to abate increasing health care expenditures although I do not believe their application will resolve the crisis. The problem today, as I see it, is that the potential quantity of health care services which could be demanded and/or delivered is virtually limitless. We need to decide what proportion of our GNP we believe should be expended for health care. This is, of course, a societal decision for which there is no "correct" answer. Having decided what we, as a society, are willing to spend, we need to identity mechanisms to decide what services will be provided and paid for and to identity mechanisms to assure greater equity in services made available to the population.

7. Do you believe that the recent outbreak of cholera in Peru is an isolated incident, or could it be a sentinel event of future problems in world health? If the latter, what role should the United States play in addressing this potential international problem?

ANSWER: Cholera in Peru, dengue hemorrhagic fever in the Caribbean and, indeed AIDS, represent important infections which have recently spread from their traditional endemic loci. More extensive and rapid travel coupled with increasing populations in both urban and rural areas provide heightened opportunities for the spread of infection. Moreover, from our knowledge now of the mechanisms of microbial replication and the frequency of mutations, it is now a certainty that we can expect periodic development of new infections. Thus, we must anticipate an on-going series of new microbial challenges.

The U.S. has, by far, the most extensive and creative biomedical research base to address these problems and the largest and most experienced cadre of epidemiologists to define such problems in the field. It is, thus, incumbent upon the United States to take a lead role in helping to mobilize needed resources internationally.

However, a strategy is needed to decide how best to detect, to characterize and to contain, in an early and timely manner, new and emerging microbes whose character and manifestations cannot be accurately forecast. To this end, the National Academy of Sciences has established a Committee on Microbial Threats to Health which plans a report in 18 months time which will provide an evaluation of the problem and a specific strategy to address it. I am now working closely with that Committee.

Senator GORE. We are anxious to hear from you. Please proceed.

STATEMENT OF DONALD A. HENDERSON

Dr. HENDERSON. Thank you, Senator Gore.

For me it is indeed an honor to be nominated to this position. I have a great respect for Dr. Bromley and for the Office of Science and Technology Policy. I very much look forward to working with Dr. Bromley and my colleagues, if indeed confirmed.

I do not have a formal statement, Senator. I would be happy to respond to any questions you might have.

Senator GORE. Already you are off to a good start here in many ways. We will look forward to hearing from you often before this subcommittee.

I do have a few questions and I will go through several different areas of policy.

First, in the area of biotechnology, on February 19th Vice President Quayle's Council on Competitiveness issued a report on national biotechnology policy. I have long been a supporter of a strong U.S. biotechnology industry, but parts of this report caused me some concern.

Why does the report say that the goal, and apparently the only goal, of Federal policy should be to "Avoid excessive restrictions" on the biotechnology industry. Should there not be some mention of public safety?

And should this be taken as an indication that the White House shares this view that the only goal is to get rid of the restrictions and we do not have to retain the focus on public safety?

Dr. HENDERSON. Thank you very much, Senator. I personally was not involved with that report. But I have read it. And I do think it is a good report.

One of the issues that relates to safety is the perception on the part of a number of groups and individuals that anything that is done as recombinant technology, anything which is done which alters cells or proteins implies a great risk.

Special and excessive restrictions proposed to address perceptions of some whom I think are unduly concerned. We are all concerned that whatever is made available in the way of a drug or a pesticide or whatever we introduce into the food chain is going to be safe and effective.

But I think we must realize that nature is at all times changing the genetic structure of, be it, organisms or plants or what have you. We ourselves have been actively engaged in improving our various cultivars, as they are called, to try to improve them.

In the course of this we have been actively engaged in changing, if you will, the genetic stock that is there. We see biotechnology as being a more focused way of making appropriate changes without having many unexpected changes.

I think the statement, avoiding excessive restrictions, should not be interpreted as having no restrictions, but rather, as having appropriate restrictions. To be concerned about any product, whatever it is that we develop through biotechnology, to be assured that this is safe, that it is not something that is going to spread unchecked or cause adverse damage has got to be uppermost in our minds.

I have the sense from my brief period in the Office that this is clearly everyone's concern. So I would not read too much into the phrase, ''avoid excessive restrictions.''

Senator GORE. Okay. My other question on biotechnology were focused in the same area. I am going to take your own statement, which includes a strong emphasis on ensuring the public safety as a de facto affirmative response to the question should there not be some emphasis on public safety in a policy with which the entire Administration is associated.

Given the Competiveness Council's overwhelming focus, virtually exclusive focus, on deregulation, which has a certain political valence, but lacks the balance contained in the statement you just gave, I do not think there is much reason for groups that follow these issues to feel that that balance was reflected in this report. But I do think your response is balanced.

When that report says, and I quote, "Regulations and guidelines affecting biotechnology are to be based solely on the potential risks," who does the Administration believe should judge those risks? Will a wide range of public participants and scientists have an opportunity to participate in these decisions? Or do you think it is best that process be a closed process, limited to a few Administration officials?

Dr. HENDERSON. Senator, I am getting acquainted myself with all the regulatory procedures of Government. But it is my understanding that in cases where one is deciding on risks, that this is done by the separate agencies. It is an open process in which there is the opportunity for input from all different components of the community.

It should not be a closed process. That would be a grave error.

Senator GORE. When the Quayle report was being prepared industry groups were closely consulted. Public advocacy groups, environmental groups, public health groups were not only not consulted, their telephone calls were not returned when they took the initiative to inquire as to how they could participate in this process.

I think that is a serious mistake. If the biotechnology industry is to advance, then these concerns must be grappled with openly, sincerely, publicly. We should not fear the participation of those who raise these concerns.

We should count their participation as a measure of our strength as a society that we have men and women of earnestness and good will who are willing to spend their time helping us to identify the kinds of questions that have to be

answered and not see them as rabble-rousing trouble makers who are out to stop all progress.

No doubt on the extremes, in any groups you can find people who feel the only way to make their point is to play that role, but 99 percent of the people who are raising these questions are extremely thoughtful and have become quite concerned during the last 50 years of the scientific revolution when our cleverness seems to have outpaced our wisdom and many new powers are deployed in our effort to command nature to do our will, without us having always used the foresight and considered reflective judgment to anticipate a lot of the problems that occur.

We are limited in our ability to foresee all these unanticipated consequences. People are out there willing to help us do that. As a society, boy, we ought to recognize that as a fantastic resource and engage them in the dialogue. And through that means, build the support for further advances.

I personally believe the whole notion of progress is coming under attack partly because we have been willing to ignore the unanticipated consequences, which often include negative byproducts or side effects. And they accumulate unseen until suddenly they come to our attention, shattering the confidence of people who had, up until that time, given their wholehearted endorsement to science and technology and the advance of the frontiers of knowledge, causing them to believe the only thing they can do is dig in their heels and say no more, we are not going to advance.

We have to rebuild a dialogue among ourselves on ways to balance the good and the bad and ways to anticipate the wanted and the unwanted. And Government's role, and in this area you are going to be perhaps the one person who will be able to give his undivided attention to these issues, is one of the opportunities, perhaps the most important opportunity, for our society as a whole to really examine these questions.

And one of the tools available to Government to play that role is the process for approving this or rejecting that or funneling money here or denying it there. That process, mechanistic as it is, offers a chance to get different views and to invite people to participate, and again not to fear them, but to welcome their views and have confidence in your ability to deal with the concerns they raise.

The Vice President's process was sorely deficient in that regard. I welcome your statement of general principle that you believe that openness is a good approach on these matters.

Dr. HENDERSON. Senator, if I may make just an observation on this. I cannot comment on the procedures used in the President's Council as I am really not acquainted with them, but I do believe an open process is important.

As I look at biotechnology and see the potential of what can be done, one sees a new frontier of tremendous potential. As one thinks back to an earlier time when Columbus set sail across the ocean, there were many who felt that was quite the wrong thing to do and that the world was flat and he was going to sail over the edge.

Senator GORE. Actually, if I could interject there? I made that statement and I was correct just a couple of months ago. The history of science, I was surprised to find, indicates that by 1492 the civilized world had pretty much concluded that, indeed the Greeks had been right 1,000 years, 2,000 years earlier, that the world was round.

And they were also right in calculating the approximate circumference of the Earth within 100 miles as the Greeks had done. Columbus mistakenly felt that the circumference of the Earth was 1/3rd smaller than it was. And it was for that

reason that he felt the number of provisions in his ships were sufficient to carry him all the way around to India.

And the learned objections to his folly were based primarily on the view that since the Earth was 1/3rd larger than Columbus mistakenly believed, he and his men would starve to death in the middle of the great, unknown ocean before he could possibly get to India. He was just soft-headed in his obstinate view that the Earth was so much smaller. And, of course, serendipitously he discovered India, what he thought was India, before he could halfway around.

I am sorry to interject that, but it was painful for me to hear that. Excuse me. Go ahead.

Dr. HENDERSON. I appreciate the history lesson.

But I think with great frontiers—and electricity is another example—we are looking at a challenge, and yet a concern. From the standpoint of those of us concerned with biotechnology we have not yet done an adequate job in broadly educating a population about not only the potential but what is involved in biotechnology—what we need worry about, what we need not worry about—because there are outcomes that people worry about that really are quite implausible. There are other things which are very plausible which deserve worrying about.

There is, as you know, a need to educate a population in the regulatory process and the why of decisions. There is need for an opportunity to work through objections and to provide a rationale and a background for the rationale which can prove an educative role.

So I would be quite supportive of your statement and I would hope we could proceed in that manner both in the regulatory process and in a broader educative sense.

Senator GORE. Just to conclude this biotechnology section, again from the Vice President's report their recommendations include recommendation 2-3: "The administration should oppose any efforts to create new or modify existing regulatory structures for biotechnology through legislation. Any adjustments can be accomplished through policies and regulations based on the four principles of regulatory review."

I think the attitude contained there shows a distrust of Congress, a distrust of the public's representatives, and I think that it is then no surprise that public groups begin to question the administration's sincerity in this field and the industry's sincerity, so I would hope you would add that to your agenda. You have addressed this already, but I want to call it to your attention.

You mention cultivars in your first response on biotechnology. It is true, is it not, that science has never created a new gene, but merely recombined genetic elements found in the wild, correct?

Dr. HENDERSON. That is correct.

Senator GORE. It is true, as well, that our plant, our food crops, depend upon genetic diversity to fight off more rapidly evolving pests, including blights and the like, correct?

Dr. HENDERSON. Absolutely.

Senator GORE. Is it also true that—well, to set up the basic model, the rate of evolution in plant crops is only a small fraction of the rapid rate of evolution in the pests and blights which attack them, correct?

Dr. HENDERSON. I am not sure that one could quantitate speed. I would say by and large there is a balance between the survival of a plant and the development of pests which are apt to destroy it, and there is continuing evolution. The plant evolves to combat the pest, but the pest then adapts to better attack the plant.

Senator GORE. Except that when we grow crops in a monoculture, the only way they evolve is with our assistance, correct?

Dr. HENDERSON. That is right.

Senator GORE. Are you familiar with this issue at all? If not, we can explore it at another time.

Dr. HENDERSON. My acquaintance with the agricultural field has primarily come through service with the Research Advisory Committee for AID over a number of years. I am certainly not an expert in the agricultural field.

Senator GORE. All right. Well, we can explore this on another occasion, after you have sunk your teeth into these issues. I will just briefly summarize the point that I was headed toward in the question and answer format.

If we focus on biotechnology as a source of genetic robustness in the plants we use especially for food crops, I believe we should have some humility about the degree to which we can engineer new varieties compared to what nature can do in engineering new varieties. Rather than put all of our eggs in the basket of gene banks and biotechnology laboratories, we should recognize that a far greater source of diversity is in the wild.

Take wheat as one example, about 10 percent of the genetic variety in the wheat genome is in the strains that are planted commonly. About another 30 to 40 percent is in the gene banks around the world, and each year, when the pests and blights have evolved to attack the species that dominates in this year's crop, the seed companies will have to go back to the labs and search the gene banks for a new variety that is robust against the new blights and pests that are attacking it.

About every ninth or tenth year, they come up dry and they do not have a new variety, so they have to look in the other 50 to 60 percent of the wheat genome. The point I am driving at is that it is sheer folly in my personal opinion, to allow our focus on biotechnology in agriculture to induce a kind of technological hubris that blinds us to the extreme value of that more than half of the resource which is and must remain in the wild, all the while encroaching upon it, destroying where it is found.

I will move on and we will talk about that another time.

Dr. HENDERSON. If I may just comment, I believe what has been common experience across the field to biotechnology is initially great excitement in realizing what could be done in terms of changing certain characteristics in plants or in organisms.

As time has moved on—and one can cite the example of our adventures with the human immunodeficiency virus—there was initially great confidence that we could move very rapidly to the development of a vaccine, that we could move very quickly to identify particular sites which could be targeted by a drug, only to find very soon that the view was a far more complicated organism than we had originally believed.

In brief there has traditionally been an initial burst of enthusiasm and expectation and then a backing away and becoming much more humble as to what we can do. The record shows that for developing better plant materials we need to rely on naturally occurring banks. And this relates to concerns for biodiversity and the need to create banks of materials for the common food products.

You are quite right. There is initially a feeling, look what we can do, we have got it all in our hands, we can do it all, to then trying to begin to make some of the changes that one can envisage and be humbled to realize it is far more complicated Nature is rather more complicated than perhaps we initially give it credit for.

Senator GORE. Yet we as a civilization are busily bringing to a close the cenozoic era of the last 65 million years with the elimination of as many as half of all the living species on earth within the lifetimes of people now alive, and they do not return once they are gone.

Dr. HENDERSON. That is right.

Senator GORE. It is an event which, if allowed to continue, would take on the order of 100 million years for the earth to heal. So while we congratulate ourselves on the cleverness in biotechnology, let us balance it with an awareness of the horrific crime that is now underway. It is not your responsibility that this White House is the principal impediment to the world community's efforts to address this question, and I mean no rhetorical aggression toward you in making that statement, but it is nonetheless a fact.

You brought up AIDS, which is undoubtedly the worst epidemic of the late 20th Century, and the pain and suffering it has caused are just incalculable. I have heard estimates that project that as many as one in three or one in four people in some African countries may die from the disease.

I was in East Africa a few months ago, and met with the leaders of the AIDS project in Kenya. Of course, Kenya is not the hardest hit, but is being very hard hit. Uganda and the Central African Republic and others are the ones that are really bearing the brunt of it now, and of course we all know what AIDS is doing in our country.

It should not comfort us to know that scientists simply cannot explain why it is so predominantly heterosexual as a primary means of its spread in those countries hardest hit and not here. It only should serve as a warning that a slight mutation in the virus could mean the consequences could be even worse for even more people here in the United States.

Do you think more research money would accelerate the discovery and production of a vaccine for AIDS? You addressed this obliquely a moment ago. What about medications to treat those people who are already infected with the virus? Are there new drugs besides AZT that offer hope for more effective treatment?

Dr. HENDERSON. Senator, AIDS is a problem which has worried us all. At Hopkins we have one of the largest academic centers doing research in this area, so that I have followed it somewhat more closely, perhaps, than some other disease problems.

As to the question of heterosexual spread the evidence is becoming increasingly clear that the presence of other sexually transmitted diseases as is prevalent in many areas of Africa, is a factor in facilitating transmission in a way that we do not see in this country.

It says to us that we ought to be paying more attention to other sexually transmitted diseases. We are not paying enough attention at this time.

Senator GORE. Do you believe that is the principal reason for the different social geography of the disease there, rather than differences in the virus strains themselves?

Dr. HENDERSON. Right. From evidence we have with regard to strains, there is no indication that the African strains are significantly different. The extensive spread is largely explained by other sexually transmitted diseases which facilitate spread.

There is also increased transmission by needles and syringe. There are in Africa lay persons called inoculators, who will inoculate almost anything on request, whether it is vitamins or antibiotics or whatever. They usually have only one needle and syringe. This results in a lot of cross-contamination.

Pattern of spread of AIDS in Africa is a complex one and I regret to say it is not as well understood as it could or should be. It would be helpful if we had a better knowledge of it.

As to the question of putting more money into the AIDS program we should be continually examining the question as to whether we would advance further with more money. I can say that in the early days of the AIDS research program, there was more money than there were good proposals . Some pretty marginal work was funded which really did not advance understanding.

This is inevitable in a new field when one tries to find who can do good work, who wants to do good work. At an early stage we had much more money than good ideas.

Looking at it now, and from discussions with Dr. Fauci, who is Director of the National Institute of Allergy and Infectious Diseases, I have the sense that we have a pretty good balance in terms of the amount of money needed and talent to address the problem. It is difficult to see how much more rapidly one could move ahead.

There are developments in other areas of basic science which contribute to our understanding of AIDS, and vice versa. It is difficult to see how much more rapidly we could move ahead in this field, particularly because HIV is a very peculiar virus and it just takes time to sort out a lot of basic science before one can figure out how best to develop a drug or vaccine.

In my opinion, at this point in time, we are in a good balance in terms of money available and money optimally spent.

Senator GORE. Let me shift the focus a little bit. I and others will have questions incidently, in writing, to follow this up. They will not be especially onerous, but I hope that you will be willing to supplement some of your responses with answers in writing.

On the subject of drug addiction, I do not think anyone disagrees with the observation that this Administration's drug policy focuses much more on interdicting drug shipments than on treating addiction or looking for effective new treatments.

The costs of focusing on drug supply rather than drug demand and addiction treatment are high: more prisons; more victims of drug-related crime; the often wasted lives of the addicts themselves.

And while the administration proposes to increase research on anti-drug abuse medication by 39 percent in the coming fiscal year, that would still total less than $200 million.

In your judgment, are these current priorities correct? Should we be spending only $200 million a year on drug abuse, research and to the causes of addiction, while spending many billions on law enforcement, just as a matter of the balance between these?

We all support the spending on law enforcement, but as a matter of balance, in an effort design to get at the final result, do you think these priorities are correct?

Dr. HENDERSON. It is difficult for me to comment on the relative amounts assigned to the different areas.

Senator GORE. It will be even more difficult after you are confirmed. So we are hoping to get some answers now.

Dr. HENDERSON. Let me offer a personal view. I strongly favor education and work being done in the area of changing behavioral patterns in children at an early stage, and trying to prevent addiction. I lean toward prevention rather than treatment, and in the drug abuse field, I feel the same way.

I have had discussions on a number of occasions with our group at Johns Hopkins which has been working closely with the National Institute of Drug Abuse, on trying to find drugs that in some way could abet the treatment process or in some way to be used to get some of those who are addicted off of drugs.

This is not an easy task. As they have reflected with me, they have a drug, for example, which is an antagonist to morphine but they find that it is not useful in treating those who are on drugs. In trying to wean addicts from drugs, they find a need to substitute something which gives some sort of an emotional stimulus.

If there is no stimulus, addicts do not want to use it.

The other problem, as they have pointed out is continued participation in drug treatment program. They are doing well if they retain perhaps 20 percent or 30 percent in treatment. It is very difficult to sustain people in treatment programs. Moreover, the question of what proportion of people even seek treatment is uncertain but it is certainly a small percent of the total on drugs.

Those in the field are pessimistic about drugs alone being the optimal approach, or being, if you will, an anticipated holy grail we should be seeking.

They put a major emphasis on the need for education and motivational programs from early on at school, right on through the school years. We perhaps would be better served by devoting more resources to discovering approaches, paradigms, methods that are optimally effective in changing. That that is where the emphasis should be.

NIDA has invested in programs of this sort. There are some very encouraging results in programs now funded. The question Is. Are we doing enough in that area? I am not sure whether we are or not. I am inclined personally to doubt that we are.

Senator GORE. I really welcome that response. I think it is a very sensible one, and I wish you luck in advocating that view.

As you advocate that view, will you have a chance to participate in those discussions? Does OSTP for example have a formal connection with the Office of the Executive Branch drug czar? Do you know that?

Dr. HENDERSON. Senator, I have no idea.

Senator GORE. Maybe you could answer that one in writing, afterwards——

Dr. HENDERSON. I would be happy to.

Senator GORE. And ask Dr. Bromley's chief of staff to help you with that one because I think you should have a formal connection. I think that you ought to be able to help set the priorities because you know the research in this area, you know the people doing it, and ought to be there at the table when these priorities are set.

I have a few other questions, but I would like to yield at this point to our ranking Republican member, Senator Pressler?

Senator PRESSLER. Good morning. I am very glad to see a person of your quality serving. We appreciate your service.

Let me ask you a question from page 5, from an answer that you gave involving the role you anticipate you will play in coordinating the various agencies involved in the Human Genome Project.

You state in part of your answer, and I quote: "In addition, the National Science Foundation and Department of Agriculture support research programs aimed at elucidating the genomes of complex organisms in the field of agriculture."

What are some of those?

Dr. HENDERSON. Senator Pressler, I am not fully conversant with that field. NSF has been funding work on a particular plant to elucidate, if you will, a total genomic structure.

And there are efforts in the Department of Agriculture and NSF to sequence and to identify the genomic structure of parts of a number of other plants. But I would be happy to reply in writing to your question.

Senator PRESSLER. All right. What are some of the main objections to expanding studies in the Human Genome Project?

Dr. HENDERSON. There has been concern expressed publicly as to whether we should be devoting large amounts of resources to one particular project as to investing such resources in investigator initiated research. This is certainly one objection.

The second objection is on the part of people who somehow or other feel that we are invading the very essence of life itself in learning about specific human genomes that we have.

To the former, the basic question is whether we should devote all of one's resources to projects which investigators initiate or whether this should be balanced with projects of a generic type.

It is my view that the human genome project and a few others, are of such importance that it is worth assigning them priority. Through the work of scientists from not only the United States but other countries, we will advance our broader understanding of a field of biology in a way we would not so do if we did not have an orchestrated type of program.

To the second part, the question of whether this project might be ethically wrong in seeking to map the determinants of the very essence of human life itself. This is a misunderstanding of what the sequencing of the human genome really represents.

There is a belief among some that this might lead to an ability to create life itself, that we would have the capability to construct humans of the type that we might like or decide is preferable.

These concerns are simply not realistic. I do not think there is any scientist who believes such outcomes to be either feasible or desirable. Thee are not ultimate objectives.

The problem here and a problem that Senator Gore referred to earlier, is that we need better education of a broader public as to what this project is, what biotechnology is and to demystify some of the aspects of it so that we understand it better. What it is and what it is not.

Senator PRESSLER. Good. At the end of the paragraph you talk about the synergistic impact of programs and resources of all interested agencies. You list such resources to include super computers, genetic data and specimens from extended families as well as funds and facilities.

Would you give an example of how a super computer would be used? Of course, it would be used to calculate the very complicated relationships, but are there additional uses of a super computer? Can you study this with just a computer? Why would a super computer be involved?

Dr. HENDERSON. I am not an expert in the application of super computers in this field. I am told by those who are that as information accumulates, as one attempts to define the structural relationships of the enormously complex genome, that the super computers will be very useful in examining both the structure and the relationship of genes.

Senator PRESSLER. How would genetic data and specimens from extended families, as well as funds and facilities, be used?

Dr. HENDERSON. Well, much of the work that has been done among family groups stems from a pioneer in this field, Dr. Victor McKusick of Johns Hopkins. He has been looking at large families to determine the pattern of particular genetic traits that they exhibit. By examining then the genes of those individuals, one

can identify where on the chromosomes there are differences between those members of the families who exhibit certain traits and those who do not exhibit certain traits.

This is a mechanism by which one begins to elucidate the sites of particular genetic defects.

Senator PRESSLER. You may have covered this already, but with regard to reports of American children developing measles and other diseases because they have not been vaccinated. In your opinion, how has the United States come to such a point that so many children do not receive basic vaccinations? I know you answered this to some extent.

What effort will you be making or will the Administration be making in this area? If you have already covered this before I got here, this is——

Dr. HENDERSON. No. We have not spoken on this. For the past year-and-a-half, I have been chairing the National Vaccine Advisory Committee which is advisory to the Assistant Secretary and to the National Vaccine Program.

One of the concerns we had was the marked increase in cases of measles during these past 2 years. In fact, last year measles cases were some six times greater than only 2 years before.

With assistance from the National Vaccine Program and others in the Public Health Service, we sought to identify why this was occurring. We ascertained very quickly that it was not a problem with the vaccine. The vaccine is as effective as it has ever been, and even though there are minor changes in the nature of the wild virus, the vaccine is fully effective.

We also ascertained that program managers had adequate vaccine; they had adequate funds for the vaccine.

Much to our surprise, we learned that the major problem rested with the health care providers. Specifically, many barriers over time have come to be raised come which inhibit young children from being vaccinated.

In part this may stem from a complacency that has grown because of the infrequency of vaccine preventable diseases during recent years and the belief they could not recur again. I believe there is now a more cavalier attitude toward providing immunization.

What we discovered is that many children were being seen in health care settings, but they were not being checked for vaccination when they were seen. In some cases, they would have a mild illness, which is not a contraindication to vaccination, but they were not being vaccinated.

And in some settings, in inner cities in particular, a mother with five children shows up at a clinic, for example, and is requested to make appointments for the children to have physical examinations before vaccination. Unfortunately, most clinics have a full schedule and the children are not seen for 3, 4, or 5 months.

We have noted repeatedly in acute care settings, in emergency rooms and other settings, that immunization is not offered. What one sees is that we have not made vaccination convenient to parents who want to get it.

We also discovered that less than half of the health insurance policies provide for vaccination. Accordingly, private physicians who are seeing children requiring vaccination are saying to their patients, instead of my providing it, go to the public clinic and you will get it for free.

This results in the parents having to make two visits for every one that they normally would have to make. Some of them are working parents who do not have the time to do this or cannot afford to take the time and to lose wages. If they go to the public clinics, this overloads the public clinics, and they, inturn, cannot serve children as well.

So we have this problem with health insurance. Less than half of the children with health insurance policies are covered for vaccination. They are insured for acne. They are insured for in-grown toenails. They are covered for everything else, but not for vaccination.

Secondly, we have found that there are a number of so- called Health Maintenance Organizations which do not provide immunization. It is almost a contradiction in terms, for an organization to call itself a Health Maintenance Organization and not offer immunization. But we have discovered that this is so as well.

We issued a report in January on the subject, we have met with the Assistant Secretary and a number of his people and we have made a number of recommendations. One of the primary recommendations is one that has to be carried out at State and local levels and in many cases by private as well as public centers, and that is to give immunization priority. Make it possible for a family to bring children into a clinic and for those children to be seen promptly and vaccinated. It is a simple approach.

And indeed, in cooperation with the American Academy of Pediatrics, with the group of primary care practitioners and the Children's Defense Fund, this message has gone out widely. How well it is being implemented, I do not know. This remains to be measured.

A number of other steps are being taken. The Public Health Service is seeking to combine vaccination with the WIC Program, with Aid to Dependent Children, and to other social benefits, and there are demonstration programs in progress.

Senator PRESSLER. I would like to say, in closing, that we currently have an outbreak of hepatitis at the Pine Ridge Indian Reservation. I have been working with a number of Federal agencies and drug companies getting vaccines out there. But many of the same problems you listed exist. It seems that certain health care steps, for some reason, are not taken by some people. But as you have outlined, it is a very complex thing.

I would appreciate it very much if you would take a look at the Pine Ridge hepatitis outbreak that is occurring at this moment. Maybe you will have some suggestions as to what we can do to prevent it in the future.

That is Pine Ridge, South Dakota, Pine Ridge Indian Reservation. It is a Hepatitis A, I believe, outbreak.

Thank you, Mr. Chairman.

Senator GORE. Thank you, Senator Pressler.

My next series of questions was going to be about vaccinations. Indeed, as we all know, Dr. Henderson is one of the foremost authorities in the world. I would only add to what Senator Pressler has brought out in his questioning of you that I hope that in your position at OSTP you will be able to help our country respond to this problem.

We hear a lot about the cholera epidemic in Peru, but we do not hear about the upsurge of epidemic diseases here in the United States. We would like very much to be kept advised on what your progress is on this.

And speaking for myself and Senator Pressler and others, we would like very much to make certain that sufficient resources are directed to those parts of our Federal effort that need them to make sure that we have not only an adequate, but a truly outstanding vaccination program.

Again, insofar as that is one of the many strengths that you bring to this position, I hope you will not be bashful or shy. I have the feeling you will not be, but I hope that you will feel empowered to move on out in that particular area especially. And please report back to us on how that is going.

I would enjoy a dialogue with you on a number of other issues, I truly would. Unfortunately, we are going to have to bring the hearing to a conclusion.

That means there will be relatively fewer questions now, but relatively more to answer in writing, if you would be so kind as to do that. These include: the development of new vaccines to policies to protect research animals; questions relating to the rundown condition of research facilities at universities; questions relating to foreign investment in American universities.

These are extremely important questions and we will look forward to reading your written answers very carefully.

Again, the committee will be acting very soon on a number of matters those of us who have participated in this hearing will be recommending to our colleagues a unanimous vote to confirm you to this position.

I wish you very well in your labors there. It truly is a privilege to have you here this morning.

This hearing is adjourned.

Dr. HENDERSON. Thank you very much, Mr. Chairman. I appreciate your confidence in me.

Senator GORE. Thank you.

[Whereupon, at 1:13 a.m., the hearing was adjourned.]

[The following information was subsequently received for the record:]

POSTHEARING QUESTIONS OF SENATOR GORE AND THE ANSWERS THERETO

1. Biotechnology. This morning we agree on the importance of public education in the development of biotechnology. I believe that we also agree that public education is a two-way street - that public participation and input in government's deliberations on biotechnology are essential I have two requests this last point. First, could you please provide for the Committee record a list of the steps that have been taken since the confirmation hearings of Dr. Bromley and Dr. Wyngaarden (with whom I had similar discussions) to improve public participation in government deliberations on biotechnology in general, and specifically to include the public viewpoint in the workings of FCCSET's Biotechnology Research Committee (BRS) and the Council on Competitiveness' Biotechnology Working Group? Second, could you please provide for the record the charter ("terms of reference") for the BRS, its agenda, and a list of the individuals now serving on it, including their titles, areas of scientific expertise, and a brief discussion of their professional backgrounds?

ANSWER: As I understand it, following Dr. Bromley's and Dr. Wyngaarden's confirmation hearings, discussions were held on the issue of public participation in activities of the Biotechnology Science Coordinating Committee (BSCC) and, more broadly, the overall role of the Committee. As you know, until he left the Directorship of the National Institutes of Health, Dr. Wyngaarden was the chairman of the BSCC. His views upon arrival at the Office of Science and Technology Policy, were that the periodic open public meetings of the BSCC were not particularly informative or productive for members or the public. Such meetings generally involved presentations from individual member agencies and very little in the way of dialogue. An attempt was made in December 1989 to hold a more constructive meeting by supplementing the formal meeting announcement in the Federal Register with letters sent to an extensive list of associations and public advocacy groups, seeking input. A sample letter and list of invitees are attached. Although the attendance was more abundant than it had been at past meetings, discussion was rather limited. As a result, Dr. Wyngaarden suggested that future open meetings focus on specific issues of interest to the public.

This proposal was tested when OSTP published in the Federal Register the document entitled, Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits. The idea was to hold an open meeting in conjunction with publication of the so-called "Scope Document" in order to gather public comments, much the same as the announcement in the Federal Register was intended. However, key representatives of environmental advocacy groups have informed informally OSTP staff that while they applauded the concept, they were not inclined to support the practice. The rationale was that the BSCC, like its successor, the Biotechnology Research Subcommittee (BRS), was not a policymaking body. The Scope Document does not have the force of regulations. Instead, OSTP was told, organizations were more interested in focusing scarce resources on public meetings sponsored by the regulatory agencies as part of the Federal rulemaking process.

There is another aspect to this question that is worth mentioning. As part of the FCCSET reorganization and revitalization, a number of changes were made in the functions of existing committees. A draft charter for the BSCC was developed that deemphasized the role of the Committee in the area of regulatory affairs. Instead, Drs. Bromley and Wyngaarden agreed that insufficient

attention had been paid to the scientific issues attendant to biotechnology, and the new chairman at that time, Dr. John Moore of the National Science Foundation, concurred. This belief has been brought forward into the current thinking on the role of the BRS. While a terms of reference has not yet been adopted, I would be happy to discuss them with you or your staff when they are finished.

OSTP also reaps the benefits of public participation though its liaison to the National Biotechnology Policy Board, a Congressionally-mandated organization administered by the National Institutes of Health. As I am certain you are aware, members of the Board represent industry, academia, state biotechnology development programs and philanthropic organizations. In addition, nine Federal agencies are represented on the Board, virtually all of which are also on the Biotechnology Research Subcommittee. This extensive network of cross-membership serves to maximize the flow of ideas and opinions while minimizing duplication of effort. The meetings of the Board are open to the public and are announced in the Federal Register.

As to your last request, I submit to you a list of the member agencies of the BRS. These are the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, State, Veterans' Affairs, and the Agency for International Development, the Environmental Protection Agency, the National Air and Space Administration and the National Science Foundation. As you can see, this is quite a significant expansion over the five agencies previously represented on the BSCC. The agencies retain the prerogative to determine their representation on a meeting-by-meeting basis, depending on the topic under discussion. As a result, I am not able to provide a list of members and descriptions of their professional expertise. However, I can do so for the Chairman, Dr. David Galas, Associate Director for Health and Environmental Research, Department of Energy, and the Vice Chairman, Dr. W. Franklin Harris, Executive Director, Directorate for Biological, Behavioral and Social Sciences, National Science Foundation. I am sure that you will agree that these two scientist/administrators are eminently well-suited to leading the BRS.

2. Drug Addiction. As we discussed at your hearing, could you please describe what formal relationship, if any, OSTP has with the White House Office of National Drug Control Policy? If no formal connection now exists, do you believe that one should be created so that the drug office receives first-rate medical advice regarding addiction and treatment?

ANSWER: The OSTP has a relationship with the White House Office of National Drug Control Policy (ONDCP) and participates in the discussions leading to the development of the National Drug Control Strategy. Dr. Bromley, as a member of the Domestic Policy Council, contributes to the development of the National Drug Control Strategy. In addition, OSTP has a direct, informal relationship with the ONDCP that could be strengthened. A principal limitation in doing so has been a lack of resources. The Division of Life Sciences has been functioning with only two professional staff, an Assistant Director and a Senior Policy Analyst. With the addition of an Associate Director and an additional Senior Policy Analyst, a greater scope of work will be possible.

3. New Vaccines. You have argued that biotechnology offers the opportunity to create new vaccines, including ones to combat the dreaded diseases of tropical Latin America, Africa, and Asia. What specific opportunities do you see here? And what specific policies or incentives do you think are needed to encourage U.S. companies to develop these badly-needed vaccines?

ANSWER: Advances in biotechnology and the biomedical sciences have proceeded at a logarithmic pace over the past decade and with these advances have come new insights into the pathogenesis of infection and of the immune response of the individual. At the same time, recombinant DNA technology now enables us to identify specific components of microorganisms which are essential to stimulating the immune response and to the design of safer, more effective vaccines. Until the 1980s, vaccine development, whether by inactivating or by attenuating a naturally occurring virus, was largely a trial and error procedure, requiring perhaps 10 to 15 years of work and testing. Today, procedures which required months to years of work have been collapsed into weeks.

Because of these developments, committees of the Institute of Medicine and the National Vaccine Program have undertaken extensive reviews of priorities and opportunities and have concluded that as many as 15 to 20 new vaccines could be available within the decade, that many of these could be combined physically or as recombinants so as to require fewer separate administrations, that many could be given in new polymer-based sustained-released preparations requiring perhaps a single administration rather than several, and that oral rather than percutaneous (by needle and syringe) administration should be feasible for many, perhaps most, of them.

Prospects beckon for a new era in effective disease prevention in America. Hepatitis, chickenpox, severe respiratory infection (respiratory syncitial virus), severe diarrhea (rotovirus), streptococcal and pneumococcal infections, sexually transmitted diseases, tuberculosis and AIDS are all likely targets. An anti-fertility vaccine, likewise, looks promising. For the Third World, there is an even more extensive list which incorporates many microbial infections not presently found in the United States.

An amazingly extensive vaccine delivery system has been developed over the past decade to the extent that by two years of age, 80% of children throughout the Third World now receive the six vaccines of the WHO/UNICEF Expanded Program on Immunization. Recently, this program has been termed the most extensive program for social action ever mounted. Poliomyelitis is now close to extinction in the Western Hemisphere and global eradication is foreseen by the year 2000—a program, incidentally, being supported, in part, by more than $200 million provided by the Rotary International Foundation.

These many events were the genesis for the September 1990 Children's Summit of world leaders and a new Children's Vaccine Initiative proposed jointly by UNICEF, the World Health Organization, the World Bank, the United Nations Development Program and the Rockefeller Foundation. The initiative calls for a global, coordinated program of research and development funded at $150 million to $1 billion over a 10-year period. Planning for this is now under way under the general direction of Dr. Phillip Russell, formerly of Walter Reed and the Army's medical research and development program.

The next decades could well usher in a new era in prevention—through vaccination. A number of significant and difficult problems need to be surmounted for this to occur, however. Because of liability problems and low profitability, American and some European producers have withdrawn from the market leaving us with only one or two producers for most vaccines. Physicians have not actively promoted immunization, in part through complacency that the major presently vaccine preventable diseases have been defeated and, in part, because most health insurance policies and some so-called health maintenance organizations inexplicably do not cover the costs of vaccination. The Act, which established a trust fund to compensate those with vaccine-associated complications, appears to have been sufficiently successful so as to attract greater industry interest in vaccine development but the interest is still tepid.

To fully exploit prospective opportunities will require a substantial infusion of research funds both for research and development, a creative set of partnerships involving government-industry-university laboratories, a more conducive regulatory environment and, for vaccines for the Third World, a far more active and effective involvement of the Agency for International Development.

Under the National Vaccine Program, a national vaccine strategy plan is now under preparation; a joint industry-government-university committee is looking at regulatory and licensing issues and a global committee is being constituted to propose a global plan. When the work of these groups has been completed, we should have a clearer idea as to what specifically needs to be done and by whom. Meanwhile, continuing support for the National Institute of Allergy and Infectious Diseases' vaccine research program and the National Vaccine Program itself is important. Proposals for enhanced support are presented in the President's budget for FY 1992.

4. Animal Research. In recent years, all of us in Congress have heard from constituents who are very concerned about the use of animals in research. They particularly object to the use of animals to develop commercial products, such as cosmetics, but as you know many citizens also object to the use of animals in biomedical research. What steps have biomedical researchers taken in recent years to reduce and, when possible, eliminate the pain and inhumane living conditions that many people believe laboratory animals experience? What more can and should be done to protect research animals? And is OSTP playing a role in developing guidelines for the protection of research animals?

ANSWER: Serious differences in views regarding the use of animals in research and in product testing have been expressed over many centuries and by many different groups. Indeed, vegetarianism and a profound respect for all life forms is the central point of certain ancient religious beliefs. Given that various such beliefs, in some form, continue to be expressed by a number of groups, some quite vocal, I believe we can expect concerns to be regularly voiced so long as animals are used by humans for any purpose whatsoever. These concerns need to be heard but not all persons can ever be fully satisfied.

Clearly, animals are needed for research, instructional and regulatory testing purposes. How their use has served and is going to improve the health of both humans and animals alike has to be communicated regularly to the public at large so that the balance in values can be more readily understood and weighed. The biomedical research community appreciates this need and is now much more actively engaged in public education efforts. Meanwhile, the Department of Health and Human Services is supporting a number of research programs to find alternatives to animal testing, specifically, activities designed to diminish the need for animal use in the laboratory. A Center for Alternatives to Animal Testing has been established at the John Hopkins which is supported by government, industry and private sources. It serves to fund research, to educate and to provide forums for discussion for those both in the private and public sectors.

The groundwork for government regulations pertaining to animal research was laid by a number of principles/guidelines for the humane care and use of laboratory animals developed by learned societies, e.g., the American Veterinary Medical Association, the American Physiological Society and the Society of Neurosciences. To help the biomedical community implement new regulations within the Animal Welfare Act and the Health Research Extension Act, the biomedical research community has been sensitized to the importance of the humane care and use of animals through a national educational effort by the Office for Protection from Research Risks of the National Institutes of Health.

This past year, OSTP worked closely with the Office of Management and Budget during the development of extensive revisions to the U.S. Department of Agriculture's animal welfare regulations, which pertain to the humane handling, care, treatment and transportation of animals. The third and final part of the final rule concerning dogs, cats and nonhuman primates was published in the Federal Register on February 15, 1991. Consistent with the President's regulatory guidelines, OSTP supported the application of performance standards in the revised regulations. Performance standards

provide greater flexibility, and enable the regulated community to develop innovative ways to achieve appropriate standards for the humane care and use of research animals.

OSTP worked with the Departments of Agriculture and Health and Human Services, as well as the Office of Management and Budget, to ensure that the animal care standards were easy to understand, in order to encourage compliance and make the standards more effective. Two new standards as required by Congress were incorporated: providing dogs an opportunity for exercise and furnishing nonhuman primates with an environment that promotes their psychological well-being. These standards have been subjected to public review and comment, and those comments were carefully evaluated in developing the final rule.

The standards for the psychological well-being of nonhuman primates require investigators who are subject to the regulations to prepare and follow a plan that takes into account the social needs of the animals involved and their opportunity to express species-specific behaviors. The plan also provides for the special needs of young animals, animals that show distress and those housed in solitary cages.

As to the future, the National Institutes of Health and the Department of Agriculture will be jointly sponsoring a series of colloquia for the research community to implement new Federal regulations regarding human animal care and use. Increased funding of USDA's Animal Plant Health Inspection Service will provide better enforcement of existing laws. Continuing support for animal facility improvement grants by NIH's National Center for Research Resources will help upgrade animal facilities.

OSTP will continue to monitor progress in dealing with this important problem.

5. University Facilities One of the more difficult science policy issues now before Congress concerns university research facilities. On the one hand, many university administrators are concerned because their research buildings are old, in disrepair, and fail to meet new requirements. On the other hand, researchers oppose cutting research grants to provide more Federal money for buildings, and some critics believe that universities already charge the government too much for indirect costs. The controversy has become particularly bitter in the biomedical field As someone who has been both a professor and a dean, where do you come down in this debate? Do you think the Federal government should use more of its limited research funds to pay for facilities? Or are buildings the responsibility of the institutions themselves?

ANSWER: One of the most difficult problems for a university administrator, especially in a private research setting, is that of obtaining resources to construct new laboratories and offices, to renovate laboratories which fail to conform to contemporary safety codes and to maintain and modernize existing facilities. It is to be noted in this regard that many laboratories constructed as recently as 1970 do not meet current standards.

At the same time, private universities, in particular, are under exceptional fiscal pressures. Education is a labor-intensive enterprise, especially so for graduate students. Tuition revenues, net of scholarships, do not cover expenditures and yet tuition costs are already so high as to make it difficult even for those in uppermiddle income brackets to meet these costs. Thus, whatever endowment revenues exist must increasingly be allocated to assure, to the extent possible, that the best qualified matriculate.

At one time, buildings at private universities were substantially financed by benefactors and foundations. After WW II and extending into the early 1970s, the Federal government made substantial contributions. For the state institutions, state governments have continued to support building and renovation but few resources have been made available to the private institutions. Over recent years, it has been my experience that ever fewer foundations are making resources available for university infrastructure, especially renovations, and donors who are able to finance new buildings, fully or substantially, are ever fewer and far between.

Established researchers have indeed protested the use of government funds for purposes which, although germane to research, do not flow into a pool of funds available for investigator-initiated grants. This reflects an understandable but parochial view of the world. Note that I use the term "established researchers", advisedly because these are scientists who, by and large, already have assigned space and see themselves benefitting little from funds provided for added or extensively renovated space.

This same group of research scientists, by and large those engaged in the basic sciences, are likewise vocal about the "exorbitant" indirect cost rates. I personally made heroic efforts to acquaint our own scientists at Johns Hopkins as to what the "indirect costs" paid for—i.e., heat, light, security, proportionate payroll and personnel costs, maintenance and housekeeping, etc. They reviewed and discussed reams of data to show how such expenses were allocated and recovered and eventually (but reluctantly) agreed that our own indirect cost rate did not, in fact, cover fully the costs of research at the school. Within weeks, however, they were declaiming in faculty meetings the "exorbitant" indirect cost rates.

The bottom line is a key policy question for the country. Do we wish, as a society, to sustain our research enterprise, particularly in private universities? If we do, we will need to ensure that adequate space, meeting necessary environmental codes, is available. At present, the availability and quality of such space is steadily declining. State institutions in most states are reasonably if not generously provided for but they understandably resent and resist state funds flowing to private institutions whose

student body is national and international in composition. Thus, I see little hope of state resources being made available to meet the needs and, as noted before, neither foundations nor private benefactors can begin to close the gap.

A large proportion of our biomedical research budget now flows to the private research universities through competitive grants. Their record of productivity, by any standard, has been exceptional. At present, however, we are drawing down on the capital investments made in earlier decades. I personally believe it would be a tragic mistake to abandon or to permit further deterioration of this national resource which has served us so well as a society.

6. Foreign Investment in American Universities. During a recent meeting of the President's Council of Advisors on Science and Technology, Dr. Bromley criticized the Japanese for recruiting individual American academics at major U.S. universities and directly subsidizing their leading-edge research. A press report quoted Dr. Bromley as saying: "They're picking off the best researchers one by one" Do you believe that foreign groups should be allowed to buy this country's best academic research, especially since most of these academics developed their expertise through U.S. taxpayers funds? What is the right way to ensure that the principal benefits of taxpayer-supported research go to this country instead of to others?

ANSWER: Some foreign countries have offered to make resources available to a number of university investigators and laboratories in exchange for having some form of access to research findings being developed in the laboratories. Different arrangements pertain in the different laboratories. How extensive this practice may be is not now known.

In principle, a closer university-industry relationship has been repeatedly identified as being important for a more rapid translation of basic research findings into commercial application. For Federal laboratories this has been encouraged by the Technology Transfer Act of 1986. Based on our own experience at Johns Hopkins, however, I can say that we have found only limited receptivity on the part of American companies in developing reciprocal agreements of this type with investigators. Japanese companies, however, have exhibited greater interest. Investigators who have reached agreements with foreign companies report that their preference would have been to work with American companies but accepted a Japanese offer, for example, in lieu of being able to identify interested American industries.

It would seem to me far preferable to have American industries benefitting from the fruits of research of American investigators but I foresee real difficulties in mandating collaborative relationships. Collaboration can be successful only if both parties have an interest in the ultimate product and the collaboration. At the same time, I would foresee both practical and political problems in seeking to preclude foreign industries from establishing relationships with independent investigators or laboratories to accomplish an objective which we see and have declared to be a laudable one.

The best option, I believe, would be to persuade American industry to make its own special efforts to develop the relationships described. Perhaps education and persuasion alone may succeed; perhaps some sort of tax incentive may be needed, at least for a few years, in order to establish the process.

POSTHEARING QUESTION OF SENATOR PRESSLER AND THE ANSWER THERETO

I would appreciate it very much if you would take a look at the Pine Ridge hepatitis outbreak that is occurring at this moment. Maybe you will have some suggestions to me and others as to what we can do to prevent it in the future. This is Pine Ridge, South Dakota, Pine Ridge Indian Reservation. It is a Hepatitis A, I believe, outbreak.

ANSWER: Following my confirmation hearing and your query about hepatitis A on the Indian reservations, I contacted Dr. Thomas Welty, the epidemiologist at the Aberdeen Area Indian Health Service. I found him to be an exceptionally well-informed person whose grasp of the problem and actions in response to the epidemic can only be described as exemplary.

Epidemic hepatitis A recurs at intervals of some 5 to 7 years on a number of Indian reservations, including those in South Dakota. Deaths due to the disease are uncommon but those affected can be quite ill. Epidemics of this sort are seldom seen among other U.S. populations but they are seen in Third World countries. Deficient sanitation and crowding are probably explanations for this phenomenon.

In the past, hepatitis immune globulin has been widely administered once an epidemic was detected. This was the only product which was of benefit. However, the globulin protected for only 3 to 4 months and repeated administrations were required.

Within the past year, at least two companies have begun limited testing of two hepatitis vaccines—a live and an inactivated one. Both look promising. Dr. Welty and his colleagues alertly seized the opportunity of the epidemic to join with the Public Health Service's Centers for Disease Control to undertake field testing of a new hepatitis vaccine produced by Smithkline and Beecham. If these show the vaccine to be satisfactorily protective, hepatitis A vaccine should be routinely provided for all Indian children and should be considered as a candidate for routine use nationally.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF SCIENCE AND TECHNOLOGY POLICY,
Washington, DC, March 8, 1991.

HON. LARRY PRESSLER
U.S. Senate, Washington, DC.

Dear Senator Pressler:

Following my confirmation hearing on Tuesday, March 5, and your query about hepatitis A on the Indian reservations, I contacted Dr. Thomas Welty, the epidemiologist at the Aberdeen Area Indian Health Service. I found him to be an exceptionally well-informed person whose grasp of the problem and actions in response to the epidemic can only be described as exemplary.

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I hope you find this information helpful.

Sincerely yours,

D. A. HENDERSON, M.D., M.P.H., *Consultant.*

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